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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

[Docket No. 2006D–0020]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Intervertebral Body Fusion Device; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device." It was developed as a special control to support the reclassification of intervertebral body fusion devices that contain bone grafting material from class III (premarket approval) into class II (special controls). The guidance document describes a means by which these intervertebral body fusion devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify the intervertebral body fusion device that contain bone grafting material from class III into class II (special controls) and retain those that contain any therapeutic biologic (e.g., bone morphogenic protein) in class III.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body

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Fusion Device" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jodi N. Anderson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3680.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 9, 2006 (71 FR 6778), FDA announced the availability of the draft guidance document entitled "Class II Special Controls Guidance Document: Class II Special Controls Guidance Document: Intervertebral Body Fusion Device." Interested persons were invited to comment on the draft guidance document by May 10, 2006.

In the same **Federal Register** (71 FR 6710), FDA published a proposed rule to reclassify the intervertebral body fusion devices that contain bone grafting material, from class III (premarket approval) into class II (special controls), and retain those that contain any therapeutic biologic (e.g., bone morphogenic protein) in class III. FDA received twelve comments on the proposed rule and

draft guidance. Ten comments were on the proposed rule and are addressed in the final rule published elsewhere in this issue of the **Federal Register**. The two comments on the draft guidance suggested that FDA clarify its discussion of device sterilization and mechanical testing. FDA has updated the guidance to clarify its recommendations about these two topics.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on intervertebral body fusion devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Class II Special Controls Guidance Document: Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1540 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and

documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets.*

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/31/07
May 31, 2007.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 07–????? Filed ??–??–07; 8:45 am]

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